

May 6, 2002

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Food and Drug Administration
5630 Fishers Lane (Room 1061)
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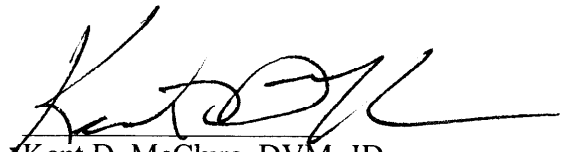
4405 02 MAY -6 P1:14

IN THE MATTER OF NOTICE OF HEARING:)
PROPOSAL TO WITHDRAW APPROVAL)
OF NEW ANIMAL DRUG APPLICATION)
FOR ENROFLOXACIN FOR POULTRY)

FDA DOCKET: 00N-1571

**PARTICIPANT ANIMAL HEALTH INSTITUTE'S
FILING PURSUANT TO 21 CFR § 12.85**

By:



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The Animal Health Institute (AHI), a non-party participant, makes this filing in accordance with 21 CFR § 12.85.

I. Documentary Filing

AHI files the documents identified in the attached exhibit A with the docket.

II. Narrative Statement

The Food and Drug Administration's Center for Veterinary Medicine (CVM) has no reasonable basis to seek the withdrawal of enrofloxacin from use in chickens and turkeys according to its approved uses. In the Notice of Hearing CVM states that the withdrawal is based upon data from "surveillance programs, published literature, and other sources." CVM asserts that its conclusion is bolstered by the so-called "temporal association," analysis of non-poultry causes of human fluoroquinolone resistant *Campylobacter* infections, and the "CVM-Vose risk assessment." However, once past the hyperbole, one finds that the surveillance data, published literature, and other available sources compellingly argue against the CVM position. CVM has entirely failed to present any reasonable or rational basis to question the safety of the use of enrofloxacin in chickens or turkeys. AHI will present evidence that shows:

The so-called "temporal association" is truly fiction and not fact. The data show that the incidence of fluoroquinolone resistant *Campylobacter* in humans occurs independently of fluoroquinolone use in poultry or other food animals. A temporal trend comparing pre- and post poultry fluoroquinolone approval data cannot be made in the US. There is simply no statistically robust dataset that contains pre- and post approval data. CVM attempts to use human and animal data from the National Antimicrobial Resistance Monitoring System to establish such an association. However, the data are not amenable to such comparisons. Notwithstanding this, if comparisons are made, the data do not support CVM's conclusion.

One is being generous to refer to the "CVM – Vose risk assessment" as indeed being a risk assessment. The "CVM - Vose risk assessment" fails to follow the National Academy of Science model for risk assessment in the federal government. CVM has bypassed critical steps, including quantification of microbial loads received by individuals and dose-response modeling. By skipping these crucial steps through assumption (called "innovative" by CVM), CVM has retreated to anachronistic days of risk assessment and embarked upon a path of speculation. CVM has failed to perform the type of "farm to fork" analysis that has become the hallmark of good risk assessment. The "CVM – Vose risk assessment" significantly overestimates any potential effect. The CVM – Vose model does not support reasonable decision-making.

CVM's belief that persons infected with a fluoroquinolone resistant *Campylobacter* infection subsequently treated with a fluoroquinolone are likely to have prolonged illness or an increased incidence of complications is baseless. CVM resorts to the unsubstantiated hyperbole that it has used repeatedly in its evaluation. The evidence will show that no break point has been set for *Campylobacter* and that data suggest that persons identified as having fluoroquinolone resistant *Campylobacter* infections by an *in-vitro* method respond clinically to treatment with a fluoroquinolone. Further, the evidence will show that there is no reasonable indication that the

course or duration or complication rates for human campylobacteriosis are affected by the *in-vitro* resistance status of the organism.

CVM has no reasonable basis for the proposed action because it has failed to consider all relevant factors and conduct the type of analysis required by law. CVM is required to conduct a risk-benefit analysis when evaluating the safety of new animal drugs. CVM implies that it has employed the food-additive standard of “reasonable certainty of no harm.” This standard specifically does not include a risk benefit analysis. As such, the evaluation by CVM is contrary to controlling case law and does not form a rational basis for action. There are human and animal health risks and economic risks associated with the proposed action that CVM has entirely failed to consider.

CVM has no reasonable basis for the proposed action because it has entirely failed to proceed in this matter in the manner required by law. CVM utilizes an *ad hoc* articulation of safety standards, as no particular standard is mandated by the Food, Drug and Cosmetic Act and CVM has never promulgated rules on the subject. *Stauber v. Shalala*, 895 F.Supp. 1178, 1191 (W.D. Wis. 1995); *American Cyanamid v. FDA*, 606 F.2d 1307, 1310, n.16, 1313-1314 (D.C. Circuit 1979). More than simply operating on an *ad hoc* basis, CVM has never clearly articulated the standard used in this proceeding. When CVM embarked upon this path utilizing an unarticulated *ad hoc* standard for safety, it became “clearly incumbent” upon CVM to give the applicant notice of the standards used and the manner in which the data before CVM failed to meet the standard. *American Cyanamid v. FDA*, 606 F.2d at 1314. Moreover, the D.C. Circuit has held that the notice must be given in a timely fashion to put the applicant in position to dispute CVM’s interpretation of the safety criteria, object to CVM’s critique of the data, and conduct and proffer new studies to meet the *ad hoc* standard. *Id.* Rather than proceeding in the required manner, CVM chose not to clearly disclose the standard used, chose not to share with the applicant the manner in which the data before it failed to meet the standard, chose not to put the applicant in a position to dispute the standard or findings in a timely manner, chose not to allow the company to conduct and proffer additional studies, and deliberately chose to withhold the data CVM claimed supported market withdrawal in a meeting with the applicant! Indeed, the sponsor learned of the data purporting to support the CVM action from the Federal Register publication of the Notice for Opportunity for Hearing. CVM’s failure to follow the procedures required by law and the responsibilities “clearly incumbent” upon it, leave no rational basis for its action.

CVM has stated that this action is predicated on the formation of a substance (fluoroquinolone resistant *Campylobacter*) formed in or on food due to the use of enrofloxacin in chickens and turkeys. There is no rational basis for CVM to conclude that presence of this “substance” on raw chicken or turkey products causes the use of enrofloxacin in chickens and turkeys to not be shown to be safe. First, it is far from clear that fluoroquinolone resistant *Campylobacter* are substances formed in or on food within the statutory meaning. Additionally, the USDA, the agency responsible for the oversight of raw chicken and turkey products, has found that the very same substance (fluoroquinolone-resistant *Campylobacter*) on the very same chicken and poultry carcasses is not a substance that may be injurious to human health or not a substance present in a quantity ordinarily injurious to health. As such, there is no reasonable basis for the proposed CVM action.

CVM has no reasonable or rational basis for this action as each of the issues raised in the Notice of Hearing was known to CVM and evaluated when CVM determined that the use of fluoroquinolones in chickens and turkeys was safe under the approved conditions of use. Close evaluation of the data generated since the approvals of fluoroquinolones in chickens and turkeys shows that it is either not credible or supports the determination that their use is safe. CVM has entirely failed to come forward with new evidence, that when evaluated with the other statutory factors, rationally supports withdrawal of the use of fluoroquinolones in chickens and turkeys.

III. CVM Burden

In both the Notice of Opportunity for Hearing and the Notice of Hearing, CVM states that its burden is merely to adduce evidence that is suggestive of an adverse effect. However, it is clear from the act itself and controlling case law that CVM has the initial burden to adduce the new evidence and what the new evidence shows. 21 U.S.C. § 360b(e)(1)(B); *Hess & Clark v. FDA*, 495 F.2d 975, 992 (D.C. Circuit 1974). CVM must initially put forth its new evidence and what it purports to show. This evidence must be supported by at least substantial evidence based upon the consideration of the entire record. *See Rhone-Poulenc v. FDA*, 636 F.2d 750, 754 (D.C. Circuit 1980); *Hendree v. Young*, 854 F.2d 1429, 1433 - 1434 (D.C. Cir. 1988). Substantial evidence is “[e]vidence furnishing a substantial basis of fact from which the fact in issue can be reasonably inferred; and *the test is not satisfied by evidence which merely creates a suspicion* or which amounts to no more than a scintilla or which gives equal support to inconsistent inferences.” *Nat’l Labor Relations Bd v. Abell Co.*, 97 F.2d 951, 958 (4th Circuit 1938)(emphasis added). Therefore, CVM’s burden is substantially greater than merely showing evidence suggesting an adverse effect.

IV. Statement of Compliance

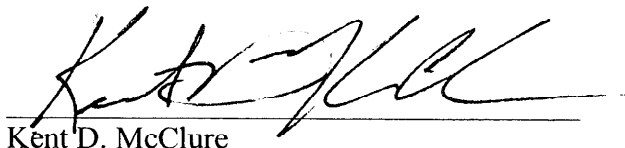
To the best of my knowledge and belief this submission complies with 21 CFR § 12.85.

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of this document was served on the following on the 6th day of May, 2002:

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Kent D. McClure

EXHIBIT A

AHI EXHIBIT LIST

Exhibit No.	<u>Title / Exhibit Type</u>	<u>Author</u>
A-1	Surveillance of the flow of salmonella and campylobacter in a community	Communicable Disease Control Section; Seattle – King County Department of Health
A-2	Transcript – Part 15 hearing, Surveillance systems for antimicrobial resistance; Vol. I	
A-3	Transcript – Part 15 hearing, Surveillance systems for antimicrobial resistance; Vol. II	
A-4	Transcript – joint meeting of the Veterinary Medicine Advisory Committee and Anti-Infective Drugs Advisory Committee	
A-5	Draft – assessment of the impacts of antibiotic resistant bacteria	Office of Technology Assessment (OTA)
A-6	Impacts of Antibiotic Resistant Bacteria	OTA
A-7	The medical impact of the use of antimicrobials in food animals	World Health Organization (WHO)
A-8	Proceedings – The role of veterinary therapeutics in bacterial resistance development: animal and public health perspectives	American Academy of Veterinary Pharmacology and Therapeutics meeting
A-9	The use of drugs in food animals: benefits and risks – Prepublication copy	National Research Council/ Institute of Medicine
A-10	Use of quinolones in food animals and potential impact on human health	WHO
A-11	The agricultural use of antibiotics and its implications for human health	General Accounting Office (GAO)
A-12	Discussion paper on antimicrobial resistant bacteria in food	Codex Alimentarius Commission
A-13	Proceedings – Antibacterial Resistance: debating animal and human health issues	IBC meeting
A-14	Antibiotic resistance in the European Union associated with therapeutic use of veterinary medicines	European Agency for the Evaluation of Medicinal Products (EMA)
A-15	Antimicrobial Resistance: an ecological perspective	American Society for Microbiology (ASM)

AHI EXHIBIT LIST

Exhibit No.	<u>Title / Exhibit Type</u>	<u>Author</u>
A-16	USDA/HHS response to the House and Senate reports: agriculture, rural development, food and drug administration, and related agencies appropriations bill, 2000	USDA/HHS
A-17	A dynamic simulation model of campylobacter illnesses: final report	Louis Anthony Cox, Jr.
A-18	Chicken derived CP infection and FQ resistance dynamic simulation Model 0.1: User guide	Louis Anthony Cox, Jr.
A-19	Preliminary notes for answers to David's questions, 6-1-00	Louis Anthony Cox, Jr.
A-20	Discrete event dynamic simulation model: summary	Louis Anthony Cox, Jr.
A-21	Risk assessment on the human health impact of fluoroquinolone resistant campylobacter associated with the consumption of chicken; 12-3-99	CVM/David Vose
A-22	Risk assessment on the human health impact of fluoroquinolone resistant campylobacter associated with the consumption of chicken; 10-18-00	CVM/David Vose
A-23	Risk assessment on the human health impact of fluoroquinolone resistant campylobacter associated with the consumption of chicken; 2-9-00	CVM/David Vose
A-24	Comments on FDA CVM Risk Model for Campylobacter	Louis Anthony Cox, Jr.
A-25	Summary of main points from Cox comments	Louis Anthony Cox, Jr.
A-26	Selected Abstracts on CP and FQ	Louis Anthony Cox, Jr.
A-27	Testing CVM's Big K model	Louis Anthony Cox, Jr.
A-28	Top 10 problems with CVM's threshold proposal	Louis Anthony Cox, Jr.
A-29	Some problems with CVM's approach to establishing thresholds for antibiotics in animals	Louis Anthony Cox, Jr.
A-30	Risk Assessment	Food Risk Clearinghouse

AHI EXHIBIT LIST

Exhibit No.	Title / Exhibit Type	Author
A-31	Codex risk assessment document	Food Risk Clearinghouse
A-32	Human feeding studies: bibliography on selected foodborne pathogens	Food Risk Clearinghouse
A-33	Hazard characterization	Food Risk Clearinghouse
A-34	Interpretive summary: Draft assessment of the relative risk to public health from foodborne <i>Listeria monocytogenes</i> among selected categories of ready-to-eat foods	FDA/USDA
A-35	Introduction: Draft assessment of the relative risk to public health from foodborne <i>Listeria monocytogenes</i> among selected categories of ready-to-eat foods	
A-36	Status of isolates in NARMS 1996, 1997, 1998 <i>Salmonella</i> , <i>E. coli</i> , and <i>Campylobacter</i> as of March 2, 1998	CDC
A-37	NARMS 1997 annual report	CDC
A-38	NARMS 1998 annual report	CDC
A-39	NARMS 1999 annual report	CDC
A-40	NARMS 2000 annual report	CDC
A-41	Chart - NARMS 1997 <i>campylobacter</i> MICs	
A-42	NARMS Veterinary isolates Final report 1998	FDA
A-43	NARMS animal <i>Campylobacter</i> isolates data – 1999	FDA
A-44	NARMS animal <i>Campylobacter</i> isolates data – 2000	FDA
A-45	FoodNet Surveillance Report for 1999 (final report)	CDC

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Exhibit No.	<u>Title / Exhibit Type</u>	<u>Author</u>
A-46	Preliminary FoodNet data on the incidence of foodborne illnesses – selected sites, United States, 2000	CDC
A-47	Risk factors for sporadic campylobacter infections in the United States: a case control study on foodnet sites	CDC
A-48	Foodnet – 1998 surveillance results preliminary report – executive summary	CDC
A-49	Status of Isolates in NARMS 1996, 1997, 1998: Salmonella, E. Coli, and Campylobacter as of March 2, 1998	
A-50	Draft – National surveillance for antibiotic resistance in zoonotic enteric pathogens	Tollefson
A-51	National and international antimicrobial resistance monitoring efforts: a description of the U.S. monitoring systems—The national antimicrobial susceptibility monitoring system. Presented at the WHO Berlin consultation Oct. 1997	Cray
A-52	The national antimicrobial resistance monitoring system: a quantitative evaluation	Ginevan
A-53	Memorandum from Dr. Carnevale regarding a meeting of the AVMA Steering Committee on Antibiotic Resistance.	Carnevale
A-54	Baytril insert	
A-55	AHI-ARS CRADA Workplan	
A-56	Comparison of three methods of antimicrobial susceptibility testing of Campylobacter spp.	Wallace
A-57	Activity of antibiotics used in human medicine for campylobacter jejuni isolated from farm animals and their environment in Lancashire, UK	Piddock
A-58	Letter to the editor, Antibiotic resistance perceptions and fact in ASM news	Lorian
A-59	Convention Seminar targets antibiotic resistance	
A-60	Implications for human health	Piddock

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Exhibit No.	<u>Title / Exhibit Type</u>	<u>Author</u>
A-61	A review: antibiotic use in animal agriculture	Gustafson
A-62	Characterization of high-level quinolone resistance in <i>Campylobacter jejuni</i>	Gootz
A-63	Incidence and transmission of antibiotic resistance in <i>Campylobacter jejuni</i> and <i>Campylobacter coli</i>	Velazquez
A-64	Review: Quinolone resistance and <i>Campylobacter</i> spp.	Piddock
A-65	Quinolone resistance in <i>campylobacter</i> isolated from man and poultry following the introduction of fluoroquinolones in veterinary medicine	Endtz
A-66	The application of quantitative risk assessment to microbial food safety risks	Jaykus
A-67	Fluoroquinolone resistance in <i>Campylobacter</i> spp isolated from human stools and poultry products	Endtz
A-68	Does the use of antimicrobial agents in veterinary medicine and animal husbandry select antibiotic resistant bacteria that infect man and compromise antimicrobial chemotherapy?	
A-69	Integronlike structures in <i>Campylobacter</i> spp of human and animal origin	Lucey
A-70	Use of filtration to isolate <i>Campylobacter</i> and related organisms from stools	Kiehlbauch
A-71	Quinolone resistant <i>Campylobacter jejuni</i> infections in Minnesota, 1992 – 1998	Smith
A-72	Antibiotic Resistance in <i>Campylobacter</i> strains isolated from animals, foods, and humans in Spain in 1997 – 1998	Saenz
A-73	Submission to Docket 98D-0969	Animal Health Institute
A-74	Supplemental Submission to Docket 98D-0969	Animal Health Institute
A-75	Submission to Docket 98D-0969	National Chicken Council

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<u>Exhibit No.</u>	<u>Title / Exhibit Type</u>	<u>Author</u>
A-76	Submission to Docket 00N-1571	Animal Health Institute
A-77	Submission to Docket 00N-1571	American Veterinary Medical Association
A-78	Submission to Docket 00N-1571	National Turkey Federation
A-79	Submission to Docket 00N-1571	National Chicken Council
A-80	Submission to Docket 00N-1571	CSPI
A-81	Submission to Docket 00N-1571	Agrimetrics
A-82	Submission to Docket 00N-1571	Hartnett
A-83	Submission to Docket 00N-1571	Glisson
A-84	Submission to Docket 00N-1571	Berndtson
A-85	Submission to Docket 00N-1571	Patterson
A-86	Submission to Docket 00N-1571	Mauff
A-87	Submission to Docket 00N-1571	Smith
A-88	Submission to Docket 00N-1571	Shane
A-89	Submission to Docket 00N-1571	TerHune
A-90	Submission to Docket 00N-1571	Poultry Council

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Exhibit No.	<u>Title / Exhibit Type</u>	<u>Author</u>
A-91	Submission to Docket 00N-1571	Elanco Animal Health
A-92	Submission to Docket 00N-1571	Kist
A-93	Submission to Docket 00N-1571	Pasternack
A-94	Submission to Docket 00N-1571 – comments	Cox
A-95	Submission to Docket 00N-1571 – discrete event simulation model	Cox
A-96	Submission to Docket 00N-1571	Haas
A-97	Submission to Docket 00N-1571	Newell
A-98	CVM Statement re: Vose Contracts	CVM
A-99	FDA response to comments on A proposed framework for evaluating and assuring the human food safety of the microbial effects of antimicrobial new animal drugs intended for use in food-producing animals	CVM
A-100	Record of events in the 14 days immediately after the 10/11/00 meeting with representative of Bayer Animal Health	Mitchell
A-101	Red meat and chicken per capita consumption	USDA
A-102	Animal production Food Safety presentation excerpt	FSIS
A-103	Briefing on Agency's efforts with respect to campylobacter	FSIS
A-104	Campylobacter jejuni	FDA/CFSAN
A-105	Freedom of Information Summary NADA 140-828	

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Exhibit No.	<u>Title / Exhibit Type</u>	<u>Author</u>
A-106	Antimicrobial Food Additives – guidance	FDA/CFSAN
A-107	Presentation by Dr. Sundlof at AHI meeting	Sundlof
A-108	Presentation by Rich Carnevale at the American Academy of Veterinary Pharmacology and Therapeutics Symposium	Carnevale
A-109	Presentation on the National Food Safety Initiative	Tollefson
A-110	Presentation on Today's Regulatory Environment for New Antibiotic Approvals and Extralabel Use at AHI meeting	Sundlof
A-111	Curriculum vitae – Mary Smith	
A-112	Curriculum vitae – Terry TerHune	
A-113	Curriculum vitae – Simon Shane	
A-114	Curriculum vitae – Mark Paternack	
A-115	Curriculum vitae – Trudy Wassenaar	
A-116	Curriculum vitae – Diane Newell	
A-117	Curriculum vitae – Gottfried Mauff	
A-118	Curriculum vitae – Manfred Kist	
A-119	Curriculum vitae – Charles Haas	
A-120	Curriculum vitae – John Glisson	

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Exhibit No.	<u>Title / Exhibit Type</u>	<u>Author</u>
A-121	Transcript - Draft Risk Assessment and the Establishment of Resistance Thresholds Workshop – December 10, 1999	
A-122	Nationwide Raw Ground Turkey Microbiological Survey	FSIS
A-123	Nationwide Raw Ground Chicken Microbiological Survey	FSIS
A-124	Nationwide Young Turkey Microbiological Baseline Data Collection Program – August 1996 – July 1997	FSIS
A-125	Nationwide Broiler Chicken Microbiological Baseline Data Collection Program – July 1994 – June 1995	FSIS
A-126	FoodNet Surveillance Report for 2000 – Preliminary Report	CDC
A-127	Minutes – Steering Committee on Antimicrobial Resistance – February 28, 2002	AVMA
A-128	Email re: NARMS	Dr. Anderson
A-129	FSIS Strategic Plan	FSIS
A-130	Safe Handling Instructions	FSIS
A-131	Resistance to Pefloxacin in <i>Pseudomonas aeruginosa</i> .	Michea-Hamzehpour
A-132	Estimating the incidence of waterborne infectious disease related to drinking water in the United States. Assessing and Managing Health Risks from Drinking Water Contamination: Approaches and Applications.	Morris

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Exhibit No.	<u>Title / Exhibit Type</u>	<u>Author</u>
A-133	The Mode of Action to Quinolones: The Paradox in Activity of Low and High Concentrations and Activity in the Anaerobic Environment.	Lewin
A-134	Isolation and Characterization of an <i>Escherichia coli</i> Strain Exhibiting Partial Tolerance to Quinolones.	Wolfson
A-135	Pharmacokinetics of Ciprofloxacin and Effect of Repeated Dosage on Salivary and Fecal Microflora.	Bergan
A-136	Emergence of Fluoroquinolone Resistance in <i>Bacteroides fragilis</i> Accompanied by Resistance to B-Lactam Antibiotics.	Kato
A-137	A Pleiotropic, Posttherapy, Enoxacin-Resistant Mutant of <i>Pseudomonas aeruginosa</i> .	Piddock
A-138	New Norfloxacin Resistance Gene in <i>Pseudomonas aeruginosa</i> PAO.	Fukuda
A-139	Development of Quinolone-Imipenem Cross Resistance in <i>Pseudomonas aeruginosa</i> during Exposure to Ciprofloxacin.	Radberg
A-140	Bactericidal Effects of Antibiotics on Slowly Growing and Nongrowing Bacteria.	Eng
A-141	Mutants of <i>Escherichia coli</i> K-12 Exhibiting Reduced Killing by Both Quinolone and B-Lactam Antimicrobial Agents.	Wolfson
A-142	Disk Sensitivity Testing for <i>Campylobacter jejuni</i> .	Eur. J. Clin. Microbiol.
A-143	Comparison of agar dilution, microtitre broth dilution and tube macrodilution susceptibility testing of ciprofloxacin against several pathogens at two different inocula.	Gombert
A-144	Effect of method, medium, pH and inoculum on the in-vitro antibacterial activities of fleroxacin and norfloxacin.	Hohl
A-145	Emergence of quinolone-imipenem cross-resistance in <i>Pseudomonas aeruginosa</i> after fluoroquinolone therapy.	Aubert

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Exhibit No.	Title / Exhibit Type	Author
A-146	Recovery of Norfloxacin in Feces after Administration of a Single Oral Dose to Human Volunteers.	Cofsky
A-147	Effects of Erythromycin and Ciprofloxacin on Chronic Fecal Excretion of Campylobacter Species in Marmosets.	Goodman
A-148	Evaluation of the In Vitro Bactericidal Action of Ciprofloxacin on Cells of Escherichia coli in the Logarithmic and Stationary Phases of Growth.	Zeiler
A-149	Impact of Oral Ciprofloxacin on the Faecal Flora of Healthy Volunteers	Enzensberger
A-150	In Vitro Activity of Ciprofloxacin against Gram-Positive Bacteria - An Overview.	Kayser
A-151	Bactericidal activity of sparfloxacin and ciprofloxacin under anaerobic conditions.	Cooper
A-152	Conditional Impairment of Cell Division and Altered Lethality in hipA Mutants of <i>Escherichia coli</i> K-12.	Scherrer
A-153	hipA, a Newly Recognized Gene of <i>Escherichia coli</i> K-12 That Affects Frequency of Persistence After Inhibition of Murein Synthesis.	Moyed
A-154	Ciprofloxacin Therapy in Cystic Fibrosis.	Scully
A-155	Current Problems in Antimicrobial Therapy for Bacterial Enteric Infection.	DuPont
A-156	Clinical Efficacy of Ciprofloxacin Compared with Placebo in Bacterial Diarrhea.	Pichler
A-157	Outer membrane changes in quinolone resistant <i>Pseudomonas aeruginosa</i> .	Hashmi
A-158	Data from the National Chicken Counsel	National Chicken Council
A-159	Influence of Season and Refrigerated Storage on Campylobacter spp. Contamination of Broiler Carcasses	Norman Stern

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Exhibit No.	<u>Title / Exhibit Type</u>	<u>Author</u>
A-160	Role of Oxygen in the Bactericidal Action of the 4-Quinolones.	Lewin
A-161	Oral Ciprofloxacin Compared With Conventional Intravenous Treatment for Pseudomonas Aeruginosa Infection Adults With Cystic Fibrosis.	Hodson
A-162	Fluoroquinolone Antimicrobial Agents.	Wolfson
A-163	Emergency of multi-drug resistance in C. jejuni	Tee
A-164	Most plants complying with Salmonella standard.	Beers
A-165	A European Study on the Relationship between Antimicrobial Use and Antimicrobial Resistance	Bronzwaer
A-166	Prevalence, biotypes, plasmid profile and antimicrobial resistance of Campylobacter isolated from wild and domestic animals from Northeast Portugal.	Cabrita
A-167	Antimicrobial susceptibility of Campylobacter and Yersinia enterocolitica isolates.	Dowling
A-168	Comparison of two agar dilution methods and three agar diffusion methods, including the Etest, for a antibiotic susceptibility testing of thermophilic Campylobacter species.	Engberg
A-169	Campylobacter and salmonella contamination of fresh chicken meat. Campylobacters, Helicobacters, and Related Organisms	Geilhausen
A-170	Short-term treatment of traveler's diarrhea with Norfloxacin: a double-blind, placebo-controlled study during two seasons.	Mattila
A-171	Antimicrobial Use and Antimicrobial Resistance: A Population Perspective.	Lipsitch
A-172	Resistance 'damage' may already be done, hard to mitigate, study says.	Osvath

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Exhibit No.	<u>Title / Exhibit Type</u>	<u>Author</u>
A-173	Illness Associated with <i>Campylobacter laridis</i> , a Newly Recognized <i>Campylobacter</i> Species.	Tauxe
A-174	Associations between Indicators of Livestock Farming Intensity and Incidence of Human Shiga Toxin-Producing <i>Escherichia coli</i> Infection.	Valcour
A-175	Gram-negative Rod Bacteraemia: function of phagocytic cells and opsonic activity of serum.	Leeuwenhoek
A-176	Increasing rates of ciprofloxacin resistant <i>Campylobacter</i> .	Sam
A-177	Concentrations of Active Ingredient in the Serum and in Tissues after Oral and Parenteral Administration of Baytril.	Scheer
A-178	Studies on the Antibacterial Activity of Baytril.	Scheer
A-179	Antibiotic resistance meeting planned for summer, Sundlof says.	Osvath
A-180	Bayer urges ALJ to release data, modify scope of hearing.	Osvath
A-181	Baytril hearing schedule extends through May 2003.	Osvath
A-182	CDC examining <i>Campylobacter</i> resistance rate increase	Osvath
A-183	A Modified Broth-Disk Antibiotic Susceptibility Test for <i>Campylobacter jejuni</i> .	Welkos
A-184	Clinical Studies on the treatment of <i>Campylobacter</i> enteritis. Emergence of quinolone resistant <i>Campylobacter jejuni</i> after treatment with new quinolones. Kasenshogaku Zasshi	Mitsuo
A-185	A placebo controlled evaluation of lomefloxacin in the treatment of bacterial diarrhoea in the community.	Ellis-Pegler
A-186	Quinolone use in animals leads to food safety problems.	Anonymous

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Exhibit No.	<u>Title / Exhibit Type</u>	<u>Author</u>
A-187	Characterization of fluoroquinolone-resistant <i>Campylobacter</i> species isolated from human beings and chickens.	Moore
A-188	Microbiological shelf-life and quality of frozen broiler chickens stored under simulated market temperatures.	Abu-Ruwaida
A-189	Infectious Disease: diarrhea.	Bruyn
A-190	Emergence of quinolone-resistant <i>Campylobacter</i> in poultry: contributing factors and underlying mechanisms	Luo
A-191	Survey of Antibiotic Usage. April 2002. National Chicken Council	National Chicken Council
A-192	NCC Fluoroquinolone Use Survey For Calendar Year 1999. National Chicken Council	National Chicken Council
A-193	Les infections a <i>Campylobacter</i> en France (1986-1997).	Megraud
A-194	Double-Blind Placebo Controlled Trial of Erythromycin for Treatment of <i>Campylobacter</i> Enteritis.	Anders
A-195	Transcript: Use of Antimicrobial Drugs in Food Animals and the Establishment of Regulatory Thresholds on Antimicrobial Resistance – Jan. 22-24, 2001	
A-196	Early antibiotic treatment of reactive arthritis associated with enteric infections: clinical and serological study.	Fryden
A-197	International Conference on Emerging Infectious Diseases 2002. Program and Abstracts Book; March 24-27, 2002	
A-198	Agrimetrics data: Turkey airsacculitis condemnation data	Agrimetrics